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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,598

06/03/2005

Andreas Meisel

BB-117

1867

23557

7590

01/23/2009

SALIWANCHIK LLOYD & SALIWANCHIK

A PROFESSIONAL ASSOCIATION

PO Box 142950

GAINESVILLE, FL 32614

EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

01/23/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/506,598

**Applicant(s)**

MEISEL ET AL.

**Examiner**

LEZAH W. ROBERTS

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15 and 17-32 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 26-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15, 17, 18 and 20-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S506)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

This Office Action is in Response the Amendment filed October 24, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claims***

#### **Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)**

Claims 15-18 and 20-25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Fong (The Journal of Infectious Diseases, 2000, Vol. 181, Suppl. 3, pp. S514-S518 as cited in the IDS) in view of Vlasselaer et al. (US 2001/0043906). The rejection is maintained in regards to claims 15, 17, 18 and 20-25. Claim 16 is cancelled.

#### **Applicant's Arguments**

Applicant submits the claims have been amended to recite "pneumonia, urinary tract infection and/or sepsis" and "anti-infective therapy is started within 72 hours following the stroke". Applicants argue the cited references, taken either alone or in combination, do not disclose or suggest the claimed invention. Neither Fong nor Vlasselaer et al. provide any hints that such anti-infective therapy would lead to a reduction of lethality and morbidity of a patient, nor do they suggest a time window within which the anti-infective therapy can be started. The attached publication states

that a preventive therapy after stroke using antibiotics is not recommended. Thus, the art as a whole actually contained disclosures that taught away from the current invention. Hindsight reconstruction has been used because Applicant's disclosure has been used to make the case of obviousness. In the current case, the cited references, either taken alone or in combination do not disclose or suggest the applicants' advantageous method.

Examiner's Response

The reference submitted by Applicant recites "Prophylactic administration of levofloxacin is not better than optimal care for the prevention of infection in patients with nonseptic acute stroke and was inversely associated with outcome at day 90". This supports the position that it would have been obvious to give a patient, who has suffered a stroke, antibiotics by disclosing an antibiotic was given to a patient to inhibit pneumonia. Further the claims encompass antibiotics in general and not just levofloxacin. The reference does not support not administering other types of antibiotics. Furthermore Fong suggests administering moxifloxacin to a patient after having a stroke. In regards to the anti-infective therapy being started within 72 hours following the stroke, normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. See MPEP 2144.05 II. It would have been obvious to administer the anti-infective agent as soon as the patient was admitted for healthcare right after having a stroke to inhibit the

onset of the infection. This would provide optimal efficacy in inhibiting the onset of pneumonia. It may also be reasonably concluded that inhibiting the onset of pneumonia would reduce lethality and morbidity of a patient merely because the antibiotics are inhibiting onset of an additional condition following a stroke.

Claims 15, 17, 18 and 20-25 are rejected.

Claims 19 and 26-32 are withdrawn.

No claims allowed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612